BILLING CODE: 4140-01-P

DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention:

Processes for Producing and Purifying Nucleic Acid-Containing Compositions

Description of Technology:

This technology consists of improved processes for producing and purifying nucleic acid-containing compositions, such as non-naturally occurring viruses, for example, recombinant polioviruses that can be used as oncolytic agents. Some of the improved processes relate to producing viral DNA templates and for chromatographic purification of nucleic acid-containing compositions, in which the nucleic acid is quantified in chromatography fractions with the rapid detection of one or more nucleic acid sequences (e.g., using real time RT-qPCR detection). In addition, the invention includes improved processes for production and purification of oncolytic poliovirus, such as PVSRIPO. Compositions generated using these methods are also described.

Potential Commercial Applications:

- Large-scale manufacturing for producing highly purified, live virus.
- Improved viral purification process that:
    - increases the yield and/or purity of the resulting product, while decreasing the purification time;
    - is generally applicable to purification of any nucleic acid molecule-containing composition, such as virus-based composition, and can be used for the purification of live native or recombinant viruses necessary for clinical applications.

- Improved process for generating viral template plasmid (such as one that includes a DNA template for an RNA virus), which addresses the problem of genetic instability of the plasmids containing the viral genome (e.g., of a recombinant polio virus) in host (e.g., bacterial) cells, in which the plasmids are typically propagated.

Value Proposition:

- Cost- and time-effective means of producing highly purified virus-based GMP products, such as oncolytic viruses, for regulatory approval.

Development Stage:

Clinical Phase I

Inventor(s):

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Intellectual Property:

HHS Ref. No. E-267-2014/0-US-01, corresponding to US Provisional Patent App. No. 62/173,777, filed June 10, 2015, entitled "Processes for Production and Purification of Nucleic Acid Containing Compositions"

HHS Ref. No. E-267-2014/0-PCT-02, corresponding to International Patent App. No. PCT/US2016/036888, filed June 10, 2016, entitled "Processes for Production and Purification of Nucleic Acid Containing Compositions"

Publications:

Ouellette *et al*., *BioProcessing J.* 2005 4(2):31-38

Related Technologies: HHS Reference #E-240-2015/0 entitled "Methods of Analyzing Virus-Derived Therapeutics"

Contact Information:

Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

Dated: August 16, 2016

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John D. Hewes

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